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May 7, 2015

The Honorable Fred Upton, Chairman
The Honorable Joe Pitts, Health Subcommittee Chairman
House Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Ranking Member
The Honorable Diana DeGette
House Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton, Ranking Member Pallone, Subcommittee Chairman Pitts, and Representative DeGette:

Thank you for the opportunity to comment as the House Energy and Commerce Committee considers the second draft of the 21st Century Cures Act. As I researched and prepared my book, "The Creative Destruction of Medicine", I became more acutely aware of the limitations of our current health ecosystem and I greatly appreciate and support the work that the 21st Century Cures initiative has done during the past year to examine ways to accelerate the discovery, development, and delivery of life-saving cures and treatments.

21st Century Cures recognizes that while health care innovations are happening at lightning speed, the current regulatory framework at the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) has delayed access to critical and life-saving technologies. This latest discussion draft has made great strides to address these issues through provisions including, the establishment of priority review for breakthrough medical devices and the streamlining of requirements for clinical trials. These efforts will go a long way in closing the gap between research advances and regulatory requirements.

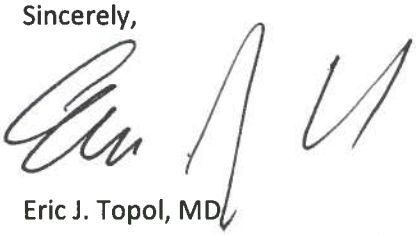
In the next draft, I encourage the Committee to address laws and regulations that block Medicare beneficiaries' access to innovative and life-saving technologies. For example, Medicare does not cover continuous glucose monitoring (CGM), an FDA-approved medical device that provides insulin-dependent diabetics with glucose readings approximately every five minutes. This technology is clinically proven to improve glucose control and reduces rates of severe hypoglycemia (low blood sugar). Although research shows that Medicare beneficiaries with insulin-dependent diabetes have disproportionately high rates of hospitalization, and hypoglycemia is the most frequent complication experienced by older adults with diabetes, CMS has determined that devices with CGM functionality do not serve a medical purpose. As such, CGM devices are not covered as durable medical equipment (DME), even though they are widely prescribed by physicians and are covered by nearly all private insurers.

I want to acknowledge that I am on the Board of Directors of Dexcom but that the views I am expressing here are independent of that relationship and fully aligned with my published work and personal opinion.

I strongly urge the Committee to ensure that Medicare beneficiaries have access to CGM devices. In the next draft of the 21st Century Cures Act, I support the inclusion of H.R. 1427, the Medicare CGM Access Act of 2015, which was introduced earlier this year by Representatives Tom Reed (R-NY), Diana DeGette (D-CO), and Ed Whitfield (R-KY). This legislation would align Medicare with the coverage offered by most private insurers, and would provide beneficiaries with access to life-saving CGM devices.

I appreciate the opportunity to submit this comment in support of the 21st Century Cures initiative, and thank the Committee for its careful attention to these issues.

Sincerely,



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